



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2005-0253; FRL-9346-8]**

**RIN 2070-ZA16**

### **Propylene Oxide; Tolerance Actions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is establishing the tree nut crop group tolerance and separate tolerances on pistachio and pine nuts for both the fumigant propylene oxide and the reaction product from the use of propylene oxide, known as propylene chlorohydrin, to cover all registered uses on raw and processed nuts. Also, in accordance with current Agency practice, EPA is making minor revisions to tolerance expressions for propylene oxide and propylene chlorohydrin.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

### **SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2005-0253. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or

other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Joseph Nevola, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; email address: [nevola.joseph@epa.gov](mailto:nevola.joseph@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for

readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-0253 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the Federal Register*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any

CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2005-0253, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Background**

### *A. What Action is the Agency Taking?*

In the **Federal Register** of December 21, 2011 (76 FR 79146) (FRL-9329-8), EPA issued a proposed rule to establish specific tolerances, and make minor revisions to tolerance expressions and specific tolerance nomenclatures for the fumigant propylene oxide and the reaction product from the use of propylene oxide, known as propylene chlorohydrin. Also, the proposed rule of December 21, 2011 provided a 60-day comment period which invited public comment for consideration.

In this final rule, in order to cover all registered uses on raw and processed nuts, EPA is establishing in 40 CFR 180.491(a)(1) tolerances for propylene oxide at 300 ppm on nut, pine; nut, tree, group 14; and pistachio; and in 40 CFR 180.491(a)(2) tolerances for propylene chlorohydrin at 10.0 ppm on nut, pine; nut, tree, group 14; and pistachio. Also, in accordance with current Agency practice, EPA is making minor revisions to tolerance expressions for propylene oxide and propylene chlorohydrin.

However, the proposed tolerance terminology changes in 40 CFR 180.491(a)(1) and (a)(2) for crop group 19 (each from dried to dried leaves) would have excluded a variety of herbs and spices in crop group 19 that are not leaves, such as pepper or poppy. Therefore, EPA has decided not to amend the current tolerance terminologies in 40 CFR 180.491(a)(1) for “herbs and spices, group 19, dried” and in 40 CFR 180.491(a)(2) for “herbs and spices, group 19, dried, except basil.”

EPA is finalizing these tolerance actions in order to implement the tolerance recommendations made in the Reregistration Eligibility Decision (RED) for propylene oxide to establish a tree nut crop group to address the lack of a tolerance for registered uses on raw nuts and conform the existing tolerance on “nutmeat, processed, except peanuts” with current Agency commodity terms. As part of the RED and tolerance reassessment processes, EPA is required to determine whether each of the amended tolerances meets the safety standard of the Federal Food, Drug, and Cosmetic Act (FFDCA). The safety finding determination of “reasonable certainty of no harm” is discussed in detail in each RED. REDs recommend the implementation of certain tolerance actions, including modifications, to reflect current use patterns, to meet safety findings and change commodity names and groupings in accordance with new EPA

policy. Printed copies of many REDs may be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), P.O. Box 42419, Cincinnati, OH 45242-2419; telephone number: 1-800-490-9198; fax number: 1-513-489-8695; Internet at <http://www.epa.gov/ncepihom> and from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161; telephone number: 1-800-553-6847 or 703-605-6000; Internet at <http://www.ntis.gov>. Electronic copies of REDs are available on the Internet at <http://www.regulations.gov> and <http://www.epa.gov/pesticides/reregistration/status.htm>.

In response to the proposed rule published in the **Federal Register** of December 21, 2011 (76 FR 79146), EPA received one comment during the 60-day public comment period, as follows:

*Comment by private citizen.* The commenter expressed concerns about pesticides on food and that only zero tolerance levels should be acceptable.

*Agency response.* The commenter did not take issue with the Agency's specific conclusions to establish certain tolerances for propylene oxide and propylene chlorohydrin. Also, the commenter did not refer to any specific studies which pertain to those conclusions. The Agency has not changed its previous determination that the tolerances in question are safe and is therefore not making any changes in response to this comment.

*B. What is the Agency's Authority for Taking this Action?*

EPA may issue a regulation establishing, modifying, or revoking a tolerance under FFDCA section 408(e). In this final rule, EPA is establishing tolerances to implement the tolerance recommendations made in the RED for propylene oxide.

### *C. When Do These Actions Become Effective?*

As stated in the **DATES** section, this regulation is effective on the date of publication in the **Federal Register**. In this final rule, EPA is establishing specific tolerances and making minor revisions to tolerance expressions for propylene oxide and propylene chlorohydrin.

### **III. International Residue Limits**

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for propylene oxide or propylene chlorohydrin.

### **IV. Statutory and Executive Order Reviews**

In this final rule, EPA establishes tolerances under FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted this type of action (i.e., establishment of a tolerance) from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has

been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-13, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, or expansion of exemptions might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis for tolerance establishments and modifications was published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account

this analysis and available information concerning the pesticide involved in this final rule, the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more

Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

## **V. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 27, 2012.

**Steven Bradbury,**

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.491 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

**§ 180.491 Propylene oxide; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the fumigant propylene oxide, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only propylene oxide, when used as a postharvest fumigant, in or on the commodity.

Commodity	Parts per million
Cacao bean, cocoa powder	200
Cacao bean, dried bean	200
Fig	3.0
Garlic, dried	300
Grape, raisin	1.0
Herbs and spices, group 19, dried	300
Nut, pine	300
Nut, tree, group 14	300
Nutmeat, processed, except peanuts	300
Onion, dried	300
Pistachio	300
Plum, prune, dried	2.0

(2) Tolerances are established for residues of the reaction product, propylene chlorohydrin, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only the sum of propylene chlorohydrin (1-chloro-2-

propanol), and its isomer 2-chloro-1-propanol, calculated as the stoichiometric equivalent of propylene chlorohydrin (1-chloro-2-propanol), that results from the use of propylene oxide as a postharvest fumigant, in or on the commodity.

Commodity	Parts per million
Basil, dried leaves	6000
Cacao bean, cocoa powder	20.0
Cacao bean, dried bean	20.0
Fig	3.0
Garlic, dried	6000
Grape, raisin	4.0
Herbs and spices, group 19, dried, except basil	1500
Nut, pine	10.0
Nut, tree, group 14	10.0
Nutmeat, processed, except peanuts	10.0
Onion, dried	6000
Pistachio	10.0
Plum, prune, dried	2.0

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